

## Efficacy of cryo-airflow therapy on calf muscle spasticity in stroke patients: a randomized controlled trial

Effect of cryotherapy on calf spasticity in stroke

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### Abstract

**Aim:** To determine the effect of cryo-airflow therapy on spasticity of calf muscle in stroke patients. **Material and Method:** This randomized control study, took place in the outpatient clinic of Mansoura General Hospital and Mansoura University Hospital, Mansoura, Egypt. Thirty stroke patients were divided into two groups and assigned randomly into the study group (n=15), which received cryo-airflow therapy, a conventional physical therapy program, and advised to wear a night ankle foot orthosis (AFO), or into the control group (n=15), which received the same program, but without the cryo-airflow therapy. Pre and post-treatment assessment for all patients was done by the modified Ashworth's scale (MAS), the Hoffman reflex / Myogenic response (H/M) ratio of the soleus muscle on the affected side, and by two-dimensional (2D) motion analysis for ankle dorsiflexion range of motion (ROM) during the stance phase of gait. **Results:** Mann-Whitney and MANOVA tests revealed a significant improvement of MAS scores ( $p = 0.006$ ) and ankle ROM scores ( $p = 0.005$ ), while the difference in H/M ratios was non-significant ( $p = 0.063$ ) in the comparison between study and control groups. Clinical and electrophysiological measures of spasticity were significantly correlated with each other ( $p = 0.765$ ) and negatively with the ankle ROM ( $p = -0.635$ ) when analyzed by Spearman correlation coefficient at ( $p = 0.000$ ). **Discussion:** Cryo-airflow therapy is considered to be an effective method to reduce spasticity in calf muscle and to improve ankle dorsiflexion ROM of the affected limb in stroke patients.

### Keywords

Stroke; Cryo-Airflow Therapy; Spasticity; Ankle ROM

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## Introduction

Many of the limitations caused by stroke are related to spasticity, a condition characterized by hyperexcitability of the stretch reflex, exaggeration of deep tendon reflexes, increased muscle tone, and loss of movement control [1]. Throughout functional movements as walking, the stretch reflex hyperexcitability becomes a part of a complex clinical condition called spastic movement disorder. In addition to spasticity, it includes the influence of other impairments, such as muscle stiffness and weakness [2]. Cryotherapy is one of the therapeutic modalities that have been considered as a mean of decreasing symptoms of spasticity [3]. Cold hypersensitivity might limit rubbing with an ice cube or packs, and it is intolerable to apply prolonged cooling or the use of evaporative agents for more than ten minutes, which may produce pain, burning sensation or thermal shock [4]. A newly developed machine that produces cold air by its passage through dry ice or by compressing the air nitrogen, it is preferable to prolonged cooling because of its continuous, constant, and accurate low temperature airflow application that can be tolerated for longer than ten minutes [4, 5]. Therefore, the purpose of this study is to determine the effect of cryo-airflow therapy on spasticity especially of the calf muscle and its effect on ankle dorsiflexion range of motion (ROM) during the stance phase of gait in patients with stroke.

## Material and Method

Patients diagnosed with cerebral stroke with calf muscle spasticity ranging from +1 to 2 according to the modified Ashworth's scale (MAS), participated in this study and were recruited from the outpatient clinic of Mansoura General Hospital and Mansoura University Hospital, Mansoura, Egypt. Forty patients were recruited, but only 30 patients were randomized and this sample size was used to achieve power analysis of 80% with alpha level (0.05). Patients were divided randomly into two groups of equal number (A and B) by a blind procedure. An independent research assistant opened sealed envelopes that contained a computer generated randomization card. Study group (A) were eight males and seven females, aged  $53.47 \pm 4.14$  years with duration of illness  $8.53 \pm 1.7$  months. Control group (B) were six males and nine females, aged  $52.40 \pm 5.67$  years with duration of illness  $8.93 \pm 2.65$  months. All patients were stable in their general health and signed a written informed consent before the study. Patients with cryoglobulinemia, peripheral artery occlusive disease, paroxysmal cold hemoglobinuria, Reynaud's phenomena, or with diabetes mellitus or other neurological or musculoskeletal deformities that interfere with gait, were excluded from this study.

The three outcome measures were evaluated for each patient individually before and after the four weeks of treatment. Group (A) received the cryo-airflow therapy and a selected physical therapy program in addition to wearing the night ankle foot orthosis. Group (B) received the same intervention as group (A), but without applying the cryo-airflow therapy. The therapeutic interventions were three times weekly, every other day regularly, (12 therapeutic sessions) for four successive weeks.

## Instrumentation & Procedures

### 1- For evaluation:

#### (a)- Modified Ashworth's scale:

It involves manually moving the ankle joint through the full range of motion to passively stretch the calf muscle during dorsiflexion [6].

#### (b)- Electrophysiological testing:

A computerized electromyographic apparatus (Section 8 Ronald S. Bienstock EMG, Inc. Serial Number 77736183, Great Britain) was used to determine the Hoffman reflex / Myogenic (H/M) ratio. Patients were placed in prone a position and the electromyographic signals from the soleus muscle on the hemiplegic side was recorded using two silver surface electrodes by stimulating the tibial nerve at popliteal fossa. The active electrode was placed over the distal one-third of the soleus muscle just below the insertion of the gastrocnemius muscle onto the Achilles tendon. The reference electrode was placed over the Achilles tendon about six centimeters above the calcaneus. A reference ground electrode was placed over the fibular head [7]. Motor neuron pool excitability which reflects the level of spasticity as an indication of central nervous system excitability is expressed by the ratio between the maximum Hoffman reflex and maximum Myogenic responses using the EMG machine [8].

#### (c) - Two dimensionals (2D) motion analysis:

Every patient was captured by video camera (Sony Video Camera Handycam HDR-CX405 1080p HD 30x Zoom, Camcorder, USA) during walking down a ten-meter walking corridor barefooted at the patient's preferred velocity [9]; in each trial, the imaging was perpendicular on and lateral to the ankle joint. The average of three trials was taken and the video captures were analyzed into a two-dimensionals plan using AutoCAD 2014 software to detect the changes in the ankle ROM post-treatment.

### 2- For Treatment:

#### (a)- Cryotherapy:

Cryo-flow 700/1000 machine (GymnaUniphy NV – Version 01/2003, Pasweg 6A, 3740 Bilzen, Belgium); a mobile therapeutic device that generates controlled dosages of cold air by extracting air from the surrounding environment and cooling it. The patient rested in a prone position and the cold air was applied to the bulk of spastic calf muscle continuously for 30 minutes with a fixed temperature that could reach about  $\leq 30^{\circ}\text{C}$  intramuscular [4]. The cryotherapy used in this study did not show any adverse effects or complications in the treated patients.

The cryotherapy was followed by selected physical therapeutic exercises to improve active ankle dorsiflexion of the hemiplegic side in the following manner: bridging exercise in supine lying position; gliding the sole of the foot on the wall up and down while lying on the non-involved side; gliding the foot on the floor forward and backward while sitting on a chair with back support; taking a step up and down on a block heel first while standing with straight back; and homolateral limb synkinesis exercise through resisted hip flexion.

Each exercise was repeated 20 times/session with five minutes rest intervals between them. All patients were instructed to wear an ankle foot orthosis on the involved extremity each night through the four weeks of the study procedure [10].

#### Data Analysis:

SPSS statistical package (v18; SPSS Inc., Chicago, Illinois, USA) for Windows was used for data analysis. Mixed design 2×2 MANOVA was used to compare the tested variables at different tested groups and training periods. Comparison of the categorical data between groups was made using the Mann-Whitney test while the Wilcoxon Signed-Rank test was used to compare pretest and post-test measurements in each group separately. Spearman's correlation coefficient was used to determine the correlations among the Modified Ashworth Scale, the H/M ratio and ankle ROM for both groups. P values less than 0.05 were considered statistically significant.

#### Results

Results of this study revealed significant effects of the independent variables (the tested groups and training periods) on the tested dependent variables ( $F=3.427$ ,  $p=0.047$ ) ( $F=28.67$ ,  $p=0.000$ ) respectively. Also, the interaction between the two independent variables was highly significant, which indicates that the effect of the tested group on the dependant variables was influenced by the training periods ( $F=7.871$ ,  $p=0.002$ ).

Within-group comparisons showed, a highly significant difference between the pre and post treatment mean ranks of spasticity grades of MAS ( $p=0.003$ ), the mean value of H/M ratios ( $p=0.000$ , 12.11% improvement) and the mean values of ankle dorsiflexion ROM ( $p=0.000$ , 21.89% improvement) within the study group. Similarly, within the control group, there was a significant difference in the mean values of MAS scores ( $p=0.003$ ), while the differences in mean value of H/M ratios ( $p=0.05$ , 3.18% improvement) and the mean values of ankle dorsiflexion ROM ( $p=0.01$ , 9.30% improvement) were less significant than in the study group (Tables 1-3).

Comparisons between both groups revealed no statistically significant difference between the study and control groups in the mean values of H/M ratios ( $p=0.435$ ), the ankle ROM ( $p=0.449$ ) and mean ranks of the MAS ( $p=0.803$ ) pre-treatment. After the treatment; the mean values of H/M ratios showed no significant difference between the groups ( $p=0.063$ ). In contrast, there was a highly significant differences in mean values and ranks of ankle dorsiflexion ROM and the MAS respectively after the treatment ( $p=0.005$ ) ( $p=0.006$ ) (Tables 1-3).

Correlation among the MAS, H/M ratio, and ankle ROM revealed a strong positive significant correlation between the MAS and H/M ratio ( $\rho=0.765$ ,  $p=0.000$ ). On the other hand, the correlation between MAS and ankle ROM was strong in the negative direction ( $\rho=-0.635$ ,  $p=0.000$ ) (Table 4).

#### Discussion

The significant improvement of the measured clinical outcomes, namely the degree of spasticity and ankle ROM, in the study group patients after the treatment intervention indicated the effectiveness of the cold air therapy in reducing spasticity in patients with stroke. Those results agree with a study

Table 1. Median score, U, Z, and P values of the Modified Ashworth Scale pre and post treatment in both groups.

Modified Ashworth Scale	Mean rank		Z-value	P-value
	pre	post		
Study group	15.17	11.6	-3.017	0.003
Control group	15.83	19.4	-3.000	0.003
U-value	107.5	54		
Z-value	-0.249	-2.766		
P-value	0.803	0.006		

P: probability value, significant level is set at alpha level < 0.05

Table 2. Mean  $\pm$ SD, P values of the H/M ratio pre and post test in both groups.

H/M ratio	Means $\pm$ SD	Means $\pm$ SD	(% of improvement)	P-value
	Pre test	Post test		
Study group	0.355 $\pm$ 0.03	0.312 $\pm$ 0.038	12.11%	0.000
Control group	0.345 $\pm$ 0.025	0.334 $\pm$ 0.021	3.18%	0.05
P-value	0.435	0.063		

P: probability value, significant level is set at alpha level < 0.05

Table 3. Mean  $\pm$ SD, P values of ankle ROM pre and post test in both groups.

Ankle ROM	Means $\pm$ SD	Means $\pm$ SD	(% of improvement)	P-value
	Pre test	Post test		
Study group	8.86 $\pm$ 1.06	10.8 $\pm$ 1.32	21.89%	0.000
Control group	8.6 $\pm$ 0.82	9.4 $\pm$ 1.18	9.30%	0.01
P-value	0.449	0.005		

P: probability value, significant level is set at alpha level < 0.05

Table 4. Bivariate correlations (spearman correlation) among the Modified Ashworth Scale and H/M ratio and ankle ROM.

	H/M ratio	Ankle ROM
Modified Ashworth Scale	$\rho=0.765$ $P=0.000$	$\rho=-0.635$ $P=0.000$

Significant at alpha level < 0.05, P: probability value,  $\rho$ : Spearman correlation

that reported that cold application could inhibits the muscle's gamma motoneurons and facilitates the alpha motoneurons, and that when the net effect of gamma inhibition exceeds the alpha motoneuron excitation, muscle spasticity is decreased [11]. Cooling the sensory nerves increases the duration of their action potential which increases the refractory period, and accordingly, decreases the number of fibers that will depolarize during the same period of time. Consequently, the frequency of pulse transmission is decreased with an increase in the threshold of nerve cells excitation [12]. It was observed that, cooling inhibits ankle clonus by slowing nerve conduction and reducing receptor activity, on both peripheral axons and muscle receptors. This indicates the significance of peripheral input with regard to central mechanisms in controlling spasticity; therefore, the simultaneous application of centrally and peripherally effective mechanisms may provide better results in treating clonus and spasticity. Moreover, "the prolonged effect of cold" support the existence of spinal adaptation and neuroplasticity in neurologically impaired subjects [13]. This idea is also supported by a previous study suggesting that, the excitability in the spinal cord may be reversely influenced by the alterations in muscles after cold therapy which in turn controls spasticity [4].

Results of this study showed that, despite the significant reduction in the H/M ratios within the study group after the treatment, there was no significant difference in the H/M ratios between the study and control groups from the beginning to the end of the treatment program. A study that was conducted to measure the sensitivity of some quantitative and qualitative measures for calf muscle spasticity after using cryotherapy aligns with our results. In that study, inconsistency between the H-reflex ratios and the decreased measures of spasticity was due to the competing effect of peripheral cooling on alpha and gamma motoneurons excitability. The authors also stated that the rise of H-reflex after cooling should not be misinterpreted because inhibitory mechanisms such as presynaptic and reciprocal inhibition are disturbed by cold, while other measures may decrease spasticity [11]. It was reported that the possible mechanism of raised H-reflex with local cooling might be the increased synchronicity of prolonged depolarization in afferent fibers. It was suggested that the changed temperature alters the opening and closing duration of sodium channels into the axon; thus, cooling decreases depolarization velocity which allows more sodium to enter the cell, increasing the latency, amplitude, and the action potential duration [14]. Moreover, it was stated that the alterations in M-wave configuration which occur due to reduced motor nerve conduction as cooling progresses, may also change the Hmax/Mmax ratio [15]. On the other hand, it was found that the increase in Hmax/Mmax ratio in spastic hemiparetic patients does not necessarily co-exist and is not related to other spasticity characteristics [16].

The significant functional improvement in ankle dorsiflexion ROM in patients of the studied groups is consistent with Boudarham et al. who revealed that hemiplegic patients with spastic foot equinus improved their gait after wearing the ankle foot orthosis. It was found that the increase in ankle dorsiflexion during the stance and swing phases was the main adaptation in the measured spatiotemporal parameters of patients' ambulation [17]. The improvement in ankle ROM in our study patients was probably due to the sustained stretching effect of the calf muscle brought about by the ankle-foot orthosis which in turn controls the calf muscle spasticity and allowed more functional ROM during gait. An earlier study is consistent with this idea, the authors found that with performing calf muscle stretching; there was a greater suppression of H/M ratio and increased duration of the electromechanical delay in the soleus muscle [18]. Patients in the control group of our study also showed quite a significant improvement in the measured outcome variables. The effect of the selected physical therapy exercises on the measured variables used with patients in this study, are undeniable. Therapeutic interventions such as active, passive or standing exercises, and positioning, could facilitates neural activity in the destructed cerebral hemisphere and are assumed to have some or all of the following effects on spasticity: decreasing the changes in the viscoelastic properties of muscle's connective tissues, changing the neural patterns of spasticity or spasms, and maintaining the levels of function for subjects complaining of spasticity [19].

The present study found a strong correlation between the H/M ratios of calf muscle EMG and its degree of spasticity as measured by the MAS scale with the biomechanical findings

of functional ankle ROM during gait. This aligns with other studies which have declared a very strong correlation between the degree of spasticity represented by the MAS scores and the electrophysiologic test results- the conventional (H max/M max) and new (H slope/M slope) measures of spinal excitability [20, 21]. On the other hand, Ghotbi et al. reported that, correlation between the MAS and either soleus (H max/M max) or soleus (H slope/M slope) was not that significant [22]. A randomized controlled trial supported our findings about the correlation between improved ankle ROM and reduced spasticity of plantarflexors, and found that ankle dorsiflexion ROM was increased after the reduction of plantarflexors' spasticity in hemiplegic patients when transcutaneous electrical nerve stimulation was applied, along with passive stretching for the plantarflexor muscles for six weeks [23].

### Conclusion

Cryo-airflow therapy is an effective modality in controlling spasticity due to its constant, long period and deep cooling effect. Exercises accompanied by the use of night AFO with or without cold air therapy can reduce calf muscle spasticity and functional ankle ROM during ambulation in patients with spasticity following stroke.

### Scientific Responsibility Statement

*The authors declare that they are responsible for the article's scientific content including study design, data collection, analysis and interpretation, writing, some of the main line, or all of the preparation and scientific review of the contents and approval of the final version of the article.*

### Animal and human rights statement

*All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. No animal or human studies were carried out by the authors for this article.*

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### Conflict of interest

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